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BROWDY AND NEIMARK, P.L.L.C.			EXAMINER	
624 NINTH STREET, NW			BRISTOL, LYNN ANNE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/524,787	EISENBACK ET AL.
	Examiner	Art Unit
	LYNN BRISTOL	1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 February 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,7,12,13,15-17,21-30,36,38,39,43-46 and 51-68 is/are pending in the application.
 - 4a) Of the above claim(s) 24-29,46,51-58,60 and 61 is/are withdrawn from consideration.
- 5) Claim(s) 59 is/are allowed.
- 6) Claim(s) 1-4,6,12,13,15-17,21-23,30,36,38,39,43-45 and 62 is/are rejected.
- 7) Claim(s) 7 and 63-68 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

1. Claims 1, 4-7, 12, 13, 15-17, 21-30, 36, 38, 39, 43-46, and 51-68 are all the pending claims for this application.
2. Claims 3, 9, 14, and 37 were cancelled, Claims 1, 13, 30, 36, and 62 were amended and new Claims 65-68 were added in the Response of 2/1/10.
3. Claims 24-29, 46, 51-58, 60 and 61 are withdrawn from examination.
4. Applicants have amended generic claim 4 by adding a Markush group listing 26 species of overexpressed polynucleotide identified in human colon carcinoma which Applicants designated as TAAs and from which the inventive peptides are obtained. Applicants have not elected a species for purposes of applying art. The original species examined was for human 1-8D gene from interferon inducible gene.
5. Claims 4-7, 12, 13, 15-17, 21-23, 30, 36, 38, 39, 43-45, 59 and 62-68 are all the claims under examination.
6. Applicants amendments to the claims have necessitated new grounds for objection and rejection. This Office Action is final.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, first paragraph

Enablement (1)

7. The rejection of Claims 15-17, 21-23, 30 and 43-45 (and now Claims 36-39) under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for an intended use for treating or inhibiting the development of colon

cancer with the inventive MHC-class I binding, CTL-inducing peptides presented as a "cell composition" is withdrawn.

As discussed during the interview of 12/17/09, and further in view of the arguments on pp. 9-10 in the Response of 2/1/10 along with enclosed reference article (Bar-Haim et al., British J. Cancer 91:398-407 (2004)), the rejection is overcome.

It is understood that an isolated APC in a composition could be made to express the genus of peptides of Claim 1, and that the claims for the composition comprising the isolated APC does not have an intended *in vivo* therapeutic use.

Enablement (2)

8. The rejection of Claims 1, 3-6, 9, 12-17, 21-23, 30, 36-39, 43-45 and 62 under 35 U.S.C. 112, first paragraph, because the specification is lacking in enablement for any peptide isolated from any protein expressed by any polynucleotide from any human colon carcinoma cell where the peptide has the ability to bind MHC Class I and elicit a peptide-specific CTL response and where the peptide optionally includes at least one non-natural modification is withdrawn.

As discussed during the interview of 12/17/09, and further in view of the arguments on pp. 11-16 in the Response of 2/1/10 along with enclosed reference articles (listed on p. 14 of the Response), the rejection is overcome.

It is understood that once the overexpressed TAA gene is identified for the human colon carcinoma as in amended Claim 1, the ordinary artisan is enabled by the specification and the art to isolate the protein, obtain the sequence, and screen the

protein sequence in art-known software programs that permit the identification of MHC Class I binding peptides and which may then be tested for CTL immunogenicity.

Enablement (3)

9. The rejection of Claims 5, 6 and 59 (and now Claims 30- 45) under 35 U.S.C. 112, first paragraph, because the specification is lacking enablement for any immunogenic peptide derived from the protein encoded by the nucleotide of SEQ ID NO:58 (human 1-8D interferon inducible protein 2) or encoded by the nucleotide of SEQ ID NO: 60 (human 1-8D interferon inducible protein 2 polymorphism) is withdrawn.

As discussed during the interview of 12/17/09, and further in view of the arguments on pp. 11-16 in the Response of 2/1/10 along with enclosed reference articles (listed on p. 14 of the Response), the rejection is overcome.

It is understood that once the overexpressed TAA gene is identified for the human colon carcinoma as in amended Claim 1, the ordinary artisan is enabled by the specification and the art to isolate the protein, obtain the sequence, and screen the protein sequence in art-known software programs that permit the identification of MHC Class I binding peptides and which may then be tested for CTL immunogenicity.

Written Description

10. The rejection of Claims 1, 3-6, 9, 12-17, 21-23, 30, 36-39, 43-45 and 62 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because Claims 1, 3-7, 9, 12-17, 21-23, and 62 (and new Claims 63 and 64) recite the

negative proviso, "*is not a six transmembrane epithelial antigen of the prostate (STEAP) protein*" in Claim 1, which does not find original support in the specification is withdrawn.

Applicants have amended the claims in the Response of 2/1/10 to delete the recitation.

Claim Rejections - 35 USC § 102

11. The rejection of Claims 1, 12, 13, 14, 15, 16, 21, 22, and 23 under 35 U.S.C. 102(a) as being anticipated by Tsang et al. (Can. Res. 61:7568-7576 (10/15/01)) is withdrawn.

Applicants amendment of claims in the Response of 2/1/10 to recite the list of 26 specific genes in Table 2 on p. 47 of the specification are not read upon and anticipated by the CEA antigen of Tsang.

12. The rejection of Claims 1, 3, 12, 13, 14, 15, 21, 22, 23 and 62 under 35 U.S.C. 102(a) as being anticipated by Trojan et al. (Lung Can. 36(2):151-158 (May 2002)) is withdrawn.

Applicants amendment of claims in the Response of 2/1/10 to recite the list of 26 specific genes in Table 2 on p. 47 of the specification are not read upon and anticipated by the Ep-CAM antigen of Trojan.

13. The rejection of Claims 1, 12, 13, 14, 15, 16, 21, 22, and 23 under 35

U.S.C. 102(b) as being anticipated by Abrams et al. (Cell. Immunol. 182:137-1515 (1997)) is withdrawn.

Applicants amendment of claims in the Response of 2/1/10 to recite the list of 26 specific genes in Table 2 on p. 47 of the specification are not read upon and anticipated by the K-ras antigen of Abrams.

New Grounds for Objection

Claim Objections

14. The claims are objected to because the lines are crowded too closely together, making reading difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1, 4-7, 12, 13, 15-17, 21-23, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1, 4-7, 12, 13, 15-17, 21-23, and 62 are indefinite for the recitation "human mRNA sequence gene" in Claim 1 because the identity of the gene is not

ascertainable from the specification or the priority document. The ordinary artisan could not determine the metes and bounds for the gene with respect to the myriad human gene sequences known and yet to be discovered that are expressed in colon carcinoma in order to practice the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposit

16. Claims 1, 4-7, 12, 13, 15-17, 21-23, and 62 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (a) known and readily available to the public; (b) reproducible from the written description.

It is unclear if a polynucleotide which comprises/encodes an mRNA and having the exact chemical identity of "the human mRNA gene sequence" of Claim 1 is known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above polynucleotide comprising the gene or a polynucleotide encoding the mRNA for the full length ORF much less encoding the immunogenic peptide, one of ordinary skill in the art could not be assured of the ability to practice the

invention as claimed. Exact replication of: (1) the claimed "human mRNA gene sequence"; (2) a gene which encodes and expresses the chemically and functionally distinct mRNA claimed; and/or (3) the claimed the immunogenic peptide encoded by the mRNA nucleic acid sequence is an unpredictable event.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Written Description

17. Claims 1, 4-6, 12, 13, 15-17, 21-23, 30, 36, 38, 39, 43-45, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4-6, 12, 13 and 62 are interpreted as being drawn to an isolated tumor associated antigen (TAA) peptide of eight to ten amino acid residues, which is capable of promoting effective binding to a MHC class I molecule to elicit a CTL response and which is encoded by a polynucleotide overexpressed in human colon carcinoma cells, which polynucleotide is selected from the group consisting of human defensin 6 gene, human ADP/ATP translocase gene, human parathymosin gene, human I-8U interferon inducible gene, human chaperonin-like protein gene, human SPARC/osteonectin gene, human I-8D interferon inducible gene, human TB2 gene, human alpha-1 collagen gene, human mRNA for dipeptidase, fibronectin gene, actin binding protein gene, HCG IV mRNA, HLA-DR antigens associated invariant gamma chain gene, MHC class I HLA-C.1 gene, polyA binding protein gene, transforming growth factor-beta induced gene, human mRNA for laminin-binding protein, human mRNA sequence gene, insulin like growth factor II gene, human ribosomal protein L23a mRNA, human acidic ribosomal phosphoprotein P1 gene, human liver mRNA fragment DNA binding protein UPI gene, ribosomal protein L37 gene, human MHC protein homologous to chicken B complex

gene and HB23 gene for B23 nucleophosmin, wherein said peptide optionally includes one amino acid substitution.

Claims 15-17 and 21-23 are interpreted as being drawn to a composition, comprising a pharmaceutically acceptable carrier, excipient, diluent or auxiliary agent and at least one peptide of claim 1.

Claims 30, 36, 38, 39, 43-45 are interpreted as being drawn to a composition, comprising a pharmaceutically acceptable carrier, excipient, diluent, or auxiliary agent, and a member which is: (A) at least one 8-10 residue TAA peptide of a tumor associated antigen (TAA) of SEQ ID NO:59 or SEQ ID NO:61, with or without one amino acid substitution; or (B) a polynucleotide encoding at least one peptide of (A), wherein said at least one 8-10 residue TAA peptide is capable of promoting effective binding to a MHC class I molecule to elicit a CTL response.

It is the examiner's position that the specification and the art do not support the breadth of scope for the peptides of the instant claims meeting all of the following structure/function criteria as required of the claims: 1) a peptide 8-10 residues in length; 2) optionally to include one amino acid substitution wherein the substitution can occur anywhere within the peptide and wherein the nature and kind of substitution is unlimited in scope; 3) the unsubstituted or substituted peptide binds to any MHC Class I molecule; and 4) the unsubstituted or substituted peptide elicits a CTL response. Accordingly, because of these deficiencies it is believed that Applicants were not in possession of the full scope of the claimed peptides at the time of application filing.

Under the Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G.

168 (Jan. 30, 2001) revised training materials 3/25/08), the claimed invention must meet the following criteria as set forth.

a) Actual reduction to practice: The specification discloses selection of HLA-A2.1-restricted peptides from human colorectal (CR)-associated genes in Table 2 on p. 47 of the specification. In addition, the 1.132 declaration filed September 18, 2008, provide evidence demonstrating that four of four single amino acid residue substitutions of peptide 3-7 (SEQ ID N0:27) and eight of eight single amino acid residue substitutions of peptide 3-5 (SEQ ID N0:25) still retain binding to HLA.A2.1, albeit at somewhat lower affinity for four of the variants of peptide 3-5 (see paragraph bridging pages 1-2 of the Summary). Accordingly, all twelve of the single amino acid substitution variants of peptides 3-7 and 3-5 tested retain binding to HLA-A2.1.

b) Disclosure of drawings or structural chemical formulas: the specification and drawings do not show that applicant was in possession of the amino acid-substituted or unsubstituted, 8-10 residue peptides encoded by the species of polynucleotides overexpressed in human colon carcinomas and having both the ability to bind just any MHC Class I molecule much less elicit a CTL response.

c) Sufficient relevant identifying characteristics: the specification does not identify 1) a complete structure, ii) partial structure, iii) physical and/or chemical properties, or iv) functional characteristics coupled with correlation between structure and function for the genus amino acid-substituted or unsubstituted, 8-10 residue peptides encoded by the species of polynucleotides overexpressed in human colon carcinomas and having both the ability to bind just any MHC Class I molecule much less elicit a CTL response.

d) Method of making the claimed invention: the specification and the prior art teach that an overexpressed TAA gene can be identified for a human colon carcinoma, the protein can be isolated and sequenced, and screened in art-known software programs that permit the identification of MHC Class I binding peptides and which may then be further tested for CTL immunogenicity. The specification and the art teach mutagenizing peptides of known structure and repeating the analysis for MHC Class I molecule binding and CTL immunogenicity.

e) Level of skill and knowledge in the art: the cloning of DNAs and domain "bashing" (i.e., generating substitution mutants for a parent peptide) for identifying functional regions within peptides having MHC Class I molecule binding properties and CTL immunogenicity was well established at the time of the invention.

f) Predictability in the Art: the specification and the art does not appear to teach where within the structure of the myriad peptides just any kind of substitution can be introduced into any given peptide yet retain MHC Class I molecule binding and CTL immunogenicity. The specification and the art do not teach which of the possible peptides resulting from a computer simulated analysis would meet all of the functional properties required of the claims.

Generally, the art acknowledges that function cannot be predicted solely on structural similarity to a protein. Smith et al. (*Nature Biotechnology* 15:1222-1223 (1997)) teach that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (*Trends in Genetics* 15:132-133 (1999)) argues that accurate inference of

function from homology must be a difficult problem since assuming there are only about 1000 major gene superfamilies in nature, then most homologues must have different molecular and cellular functions.

Finally, with respect to the number and kind of species that must be demonstrated for a genus claim, the Court in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* (Fed. Cir. 2010) (en banc) stated in part:

"a few broad principles hold across all cases"; "We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006). Conversely, we have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008), or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)."

"For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Conclusion

18. Claim 59 is drawn to the human 1-8D interferon inducible protein 2 polymorphism of SEQ ID NO: 61 and is free from prior art.
19. Claims 7, 63 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims. Claims 7, 63 and 64 are drawn to peptide 3-7 (peptide of SEQ ID NO: 27 from 1-8D interferon inducible gene protein), peptide 1-6 (peptide of SEQ ID NO: 11 from 1-8D interferon inducible gene protein), and peptide 3-5 (peptide of SEQ ID NO: 25 from 1-8D interferon inducible gene protein), respectively. These peptides have been tested in vitro and in vivo experiments with results shown in Figures 4-10.

20. Claims 65-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 65-68 are drawn to peptide of SEQ ID NO: 16 from actin binding protein (Claim 65); peptide of SEQ ID NO: 20 from human ribosomal protein L23a (Claim 66); peptide of SEQ ID NO: 21 from TGF beta induced gene (Claim 67); and peptide of SEQ ID NO: 22 from human TB2 gene (Claim 68).

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Primary Examiner, Art Unit 1643